

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ARTHREX, INC.,)
a Delaware Corporation,)
)
Plaintiff,)
)
v.)
)
INNOVASIVE DEVICES, INC.,)
a Massachusetts Corporation,)
)
Defendant.)
)

CASE NO.: 99-851-CIV-ORL-18C

DECLARATION OF ALAN CHERVITZ IN SUPPORT
OF INNOVASIVE DEVICES, INC.'S OPPOSITION TO
ARTHREX'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I, Alan Chervitz, declare as follows:

1. I am the Executive Vice President and Chief Operating Officer of Innovasive Devices, Inc. ("Innovative") a company founded in 1991 and dedicated to the development, design and commercialization of medical tool, devices, and implants, focusing in particular on medical devices used in orthopedic surgery.

2. The technology involved in the pending motion for partial summary judgment relates to arthroscopic surgical procedures used in reconstructive knee surgery to repair the anterior cruciate ligament ("ACL") of the knee. The ACL is the ligament that connects the front of the tibia (the shin bone) to the back of the femur (the thigh bone).

3. Since at least the early 1980's, orthopedic surgeons have utilized a number of different procedures to replace a damaged ACL with a graft ligament from another part of the

body. Over the years, surgeons and medical implant and tool manufacturers, including Innovasive and several others, have worked together to refine the procedures and tools available to perform ACL replacement and reconstruction. Examples of some of the current ACL replacement techniques are described in the materials attached as Exhibit B to the Declaration of E. Marlowe Goble which has been filed with Innovasive's Opposition to Arthrex's Motion for Partial Summary Judgment.

4. Beginning in the early 1990's, surgeons have begun to use a "cross-pin" technique by which an implant (the pin) is introduced transversely across the graft to hold the graft in place and/or to affix the graft to the bone. Dr. E. Marlowe Goble was the inventor of the cross-pin technique and holds several patents on his cross-pin technology. The two fundamental patents covering the cross-pin technique are Dr. Goble's U.S. Patent Nos. 5,350,380 (issued September 27, 1994) and 5,431,651 (issued July 11, 1995). Copies of these two patents are attached as Exhibits A and B hereto. The Goble patents represented a very significant advancement in the art of reconstructive ACL surgery. In September 1996, Innovasive obtained a license from Dr. Goble to practice the techniques covered by the '651 Patent. Innovasive also has a license under the '380 Patent. The '651 patent was also licensed to Arthrex as well as other medical device manufacturers.

5. Innovasive began selling a cross pin implant to surgeons after it obtained licenses under the Goble patents. Innovasive later developed its SlingShot™ System which consists of a combination of surgical instruments and implant components that operate together for use in ACL cross-pin fixation. The basic components of the SlingShot™ System include a cannulated cross pin implant for fixation of a graft within the femoral bone, a "cable graft

passer (or flexible wire) over which the implant is passed into the bone, and a "j-hook" and "crochet hook" for manipulating the wire within the tunnels formed in the knee.

6. After being served with the complaint in this action and, in particular, after being served with Arthrex's motions for partial summary judgment and for preliminary injunction, I and others at Innovasive have taken steps to investigate the inventorship of the techniques described in Arthrex's U.S. Patent No. 5,918,604 (the "'604 Patent").

Specifically, I have spoken with John McPherson, who is currently employed by Innovasive but formerly worked for a company which distributed medical products for Arthrex as well as other manufacturers. I have learned from Mr. McPherson that during the Fall 1996 Arthroscopy Association of North America conference in November 1996 he and several others discussed the technique described in the '604 Patent and ultimately embodied in Arthrex's TransFix product offering. I also learned from Mr. McPherson that at least one person utilized the technique claimed in the '604 Patent in an open cadaver laboratory available to surgeons and others at the Fall 1996 conference. I have also learned from Mr. McPherson that one or more of the people involved in the discussions about this technique at the Fall 1996 conference were either employed by Arthrex or employed by companies who were engaged as distributors for Arthrex.

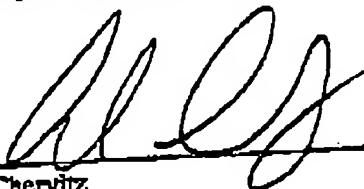
7. Attached as Exhibit C hereto is a copy of an excerpt from Orthopedics Industry Overview; Investment Opportunities in Orthopedics, dated August 6, 1998, published by Dain, Rauscher, Wessels.

8. Innovasive sells the SlingShot™ System to orthopedic surgeons for their use in performing ACL reconstruction procedures using a cross pin technique licensed from Goble.

Although the SlingShot™ System can be used to perform the general method recited in the Whelan Patent claims, its components can be used in other methods as well. Indeed, each element of Innovative's SlingShot™ system except the cable graft passes and the crochet hooks are also components of Innovative's SetScrew™ System, which is used with a bone-tendon-bone ACL graft replacement. The crochet hook is a component of Innovative's ROC™ suture fastener system. All components of the SlingShot™ System except cable graft passer were sold commercially by Innovative before it sold the SlingShot™.

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Sworn to under the pains and penalties of perjury this 14th day of October, 1999.



Alan Chervitz

Exhibit 3054406.1